

## REMARKS

### Aspects of Distinction of the Present Application with Respect to Parent Application

The Examiner is correct in his observation that the present application differs from the parent application with respect to (*inter alia*) the “hardening time”. Features of the present invention are directed and are now set forth in the claims with specificity to provide that hardening occurs within a thirty five minute time frame. This is an important aspect of the invention for fulfillment of the objectives of the invention. That is, the invention is designed for use as a bone graft or implant material in addition to tooth restoration. In other words the invention is directed to bone repair. An objective of the invention is to provide a material which will have adequate strength to achieve the desired objective. An important part of this undertaking is to provide hardening of the therapeutic material in an expedited manner i.e. thirty five minutes or less and simultaneously provide for adequate strength or toughness for the grafted material or implant. The claims have been amended to more particularly point out and distinctly claim the respective features of the composition of the invention directed to the accomplishment of these objectives.

### Amendments of Form of Claims

Independent Claims 1 and 35 have been amended by deletion of the reference to the words “in combination”. The claim is directed to the paste material which comprises the combination of component materials. Misspelling of the word “ratio” has been corrected in claim 31.

Claims 1 and 35 are the remaining independent claims. Claims 30, 31, 32, 34, 36 and 37 have been cancelled.

### Inventor and Owner Designation

The present application and all related applications are subject matter jointly developed by the jointly named inventors Lawrence Chow and Shozo Takagi. All of the

applications and the inventions associated therewith including all of the provisional applications are owned by the ADA Foundation. Inventorship and ownership of all of the inventions has been common throughout the making of the invention and throughout the prosecution of the applications. The inventors were and are employees of the ADA Foundation, a non-profit entity.

Claim Rejections – 35 U.S.C. §103

The Examiner rejected the claims as unpatentable over the combination of Tatsuzo in view of Mandai. Tatsuzo (JP 02311406) is a Japanese reference. Applicants note that the Examiner provided a full translation. Applicants have also undertaken to secure a copy of a translation of the Tatsuzo reference which is attached hereto.

As noted above, the present compositions are designed for use as bone graft or implant material for procedures such as tooth restoration and bone repair. The two independent claims have been amended to more particularly point out the compositional features of the invention. Importantly, the paste which comprises the invention is non-aqueous. Additionally the particle size of the powdered calcium compound is now set forth with greater particularity. This feature of the invention is important because it enables quick or relatively speedy but controlled hardening time upon exposure of the composition to an aqueous material. Additionally the composition exhibits significant strength or mechanical properties (DTS-diametral tensile strength) as shown in Table 3 of the application. Because the composition paste of the invention is anhydrous, it has a reasonably long storage life and yet remains useful when placed in vivo or mixed with a source of aqueous material. It becomes especially useful in the environment of bone grafting and implants where not only strength is a necessary result but speed of the hardening is essential. Thus the claimed composition is utilitarian in the desired environment of bone grafting and tooth restoration.

Applicants contend the Tatsuzo composition, which is designed for root canal filling, but not bone repair or grafts, is inapplicable and, in fact, the teachings thereof are counterintuitive relative to the subject matter of the present invention. This is borne out by a number of factors. First, the Tatsuzo reference is directed to root canal filler. Root canal fillers typically should not be very hard and thus does not demonstrate significant

strength. This is necessary so that root canal fillers can be removed should corrective dental treatment become necessary. It is therefore unlikely that Tatsuzo compositions turn into a hard mass. Second, Tatsuzo in the table at page 5 of the translation indicates curing times (not hardening times) in the range of at least two hours. Such a time delay would be deemed unacceptable with respect to the objectives of the present invention, i.e. bone grafting and tooth restoration. Applicants therefore suggest that the Tatsuzo reference does not lend itself to a solution of the problems solved by the present claims and "teaches away" from the claimed composition.

Applicants previously mentioned the use of the gelling agent which is important to preclude wet field wash out which is another necessary objective with bone grafting or implant repair. The Examiner admitted that Tatsuzo does not have such a feature and, in fact, such a feature would be unnecessary in Tatsuzo inasmuch as the composition is directed to the treatment of a root canal which would typically not encounter a wet field wash out issue. Again the combination with other art is counter intuitive.

With the present invention, applicants have found that particle size is an important feature that facilitates appropriate hardening times. The specific particle sizes have been incorporated in the claims and enable the hardening times to again meet the objectives associated with the use of the composition of the invention. Simultaneous with the hardening times, the compositions claimed provide the strengths necessary for the functional or utilitarian use of the present invention. Table 3 of the present application illustrates this aspect or feature. Again Tatsuzo and the other references do not teach any aspect of a composition having such strength let alone the compositional and physical limitations to provide such features.

The fact that the presently claimed composition is a non-aqueous paste is an important aspect of the invention inasmuch as the utility can be controlled with respect to the therapy undertaken. That is, the addition of water material to the paste composition initiates the time for the setting of the material. Control of the mixture and thus time in terms of the therapy being applied, such as bone grafting, can be more easily controlled and addressed when applying that therapy. As a paste the ease of use by mixing is facilitated. Therefore applicants respectfully urge that the described features are now

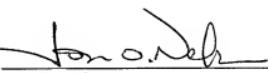
encompassed within the unique combination of limitations set forth in the independent claims 1 and 35.

In view of the foregoing, therefore it is believed that the claims in their amended form are allowable. Reconsideration thereof and passage to allowance is earnestly solicited.

Respectfully submitted,

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